PATENT COOPERATION TREATY

REC'D 28 SEP 2005
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From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2004/037867	12.11.2004	12.11.2003

International Patent Classification (IPC) or both national classification and IPC
A61F2/24

Applicant
MEDTRONIC VASCULAR, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2004/037867

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 12,14,33,34

because:

☒ the said international application, or the said claims Nos. 14,33,34 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the whole application or for said claims Nos. 12

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☒ not paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1,8-10,13,15-32

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	8-10,15-32
	No:	Claims	1,13
Inventive step (IS)	Yes:	Claims	8-10,15-32
	No:	Claims	1,13
Industrial applicability (IA)	Yes:	Claims	1,8-10,13,15-32
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 14,33,34 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to novelty, inventive step and industrial applicability (Article 34(4)(a)(I) PCT).

Re Item IV

Lack of unity of invention

Reference is made to the following document:

D1: WO 01/00114 A (SAADAT, VAHID) 4 January 2001 (2001-01-04)

The following groups of claims:

1,8-10,13,15-32:

A system for treating mitral valve regurgitation comprising the device for treating, a delivery catheter for delivering the device and a locking mechanism for locking the device in a reduced configuration. The device comprises a flexible tubular member including a through lumen and a plurality of sidewall openings and a barb assembly including a filament with a hollow configuration extending through the tubular member's through lumen and a plurality of barbs coupled to the filament and extending along the tubular member's plurality sidewalls

1,2-4:

A device for treating mitral regurgitation including a filament with the shape of a hollow tube

1,5:

A device for treating mitral valve regurgitation including a flexible tubular member with

a plurality of notches

1,6,7:

A device for treating mitral valve regurgitation including a flexible tubular member having a temporary barb disposed at its distal end and a plurality of anchors disposed around a perimeter of the flexible tubular member's deployed ring shape

1,11:

A device for treating mitral valve regurgitation including a reshaping cord being threaded through a cord ring disposed at the distal end of the device

define five different inventions. The reasons are the following:

Document D1, which represents the closest prior art, discloses an apparatus for the treatment of tissue that modifies the geometry of operation of a heart valve. It comprises a catheter with a central bore extending along its length and a plurality of sidewall openings or side bores. The apparatus comprises also an end effector made of nitinol or of a spring steel including a conductive shaft slidably mounted within the catheter's central bore and a plurality of radially extending electrodes with optionally incorporated barbs (made of nitinol or a spring steel) that extend through the catheter's side bores. When conductive shaft is slidably advanced within the catheter's central bore, the advancing electrodes with the optionally incorporated barbs engaging into the adjacent annulus through the catheter's side bores. The catheter must therefore be sufficiently flexible to be transformable between a relatively straight delivery configuration and a deployed ring with an approximate shape of an annulus of tissue such that the electrodes with the optional incorporated barbs can peripherally extend the catheter an engage the surrounding annulus tissue.

The subject matter of the first group of claims (claims 1,2,8,13,16,32) also aim to modify the geometry of operation of a heart valve, namely the mitral valve. The special technical features (as defined in Rule 13.2 PCT) of this first group of claims with relation to prior art are the delivery catheter and the locking mechanism disposed on the filament for locking the device in the ring or reduction configuration. Although not directly disclosed, it is evident for the person skilled in the art that the disclosed catheter in document D1 would

have to be delivered to the treatment site by a non disclosed delivery catheter. The locking mechanism seems to provide the tubular member with reliable capabilities for maintaining the annulus ring with the desired reduced size.

The special technical feature for the second group of claims (claims 1,2-4) is the filament assuming the shape of a hollow tube. It seems to be only a mere alternative for a filament that has to be formed into a ring shape.

The special technical feature of the third group of claims (claims 1,5) is the flexible tubular member including a plurality of notches for providing enhanced flexibility characteristics to the annulus reduction device.

The special technical features of the fourth group of claims (claims 1,6,7) which are the defined anchoring means on the tubular member, provide extra anchoring capabilities to the implanted ring during and after attachment to the valve annulus.

The special technical features of the fifth group of claims (claims 1,11) are the reshaping cord and respective ring and enable the reduction ring to conform to the valve annulus shape and size.

No same or special technical features can be determined which are common to the five groups of inventions. Moreover, the proposed solutions and problems are so different that no technical relationship can be perceived.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Although claims 16,32 have been draft as separate independent claims, they appear to relate to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and/or in respect of the terminology used for the features of that subject matter. The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of protection.

Hence, claims 16,32 do not meet the requirements of Article 6 PCT.

Due to the above mentioned multiplicity of independent claims seeking to define more or less the same invention in different ways, it seems not feasible to perform a substantive examination on all the claims. Moreover, the terms "means for reducing mitral valve annulus", "means for translating..." means for inserting...", means for locking..." used in claim 32 are vague and unclear and leaves the reader in doubt as to the meaning of the technical features to which they refer, thereby rendering the definition of the subject-matter of said claim unclear, Article 6 PCT. Independent claim 16 consequently better defines the idea underlying to the present application.

The substantive examination is therefore being based on claim 1 which discloses a device for treating mitral valve regurgitation and claim 16 disclosing a system including the previous device and subsequent dependent claims.

2. The subject-matter of claims 1,13 cannot be considered new (Article 33(2) PCT) for the following reasons:

Document D1 discloses (references in parentheses applying to this document) an apparatus for the treatment of tissue that modifies the geometry of operation of a heart valve. It comprises a catheter (82) with a central bore (86) extending along its length and a plurality of sidewall openings or side bores (88). The apparatus comprises also an end effector (84) made of nitinol or of a spring steel including a conductive shaft (92) slidably mounted within the catheter's central bore (86) and a plurality of radially extending electrodes (94) with optionally incorporated barbs (96) that extend through the catheter's side bores (88). That is, the optional barbs are also made from nitinol or a spring steel as claimed in claim 13. When conductive shaft (92) is advanced within the catheter's central bore, the advancing electrodes (94) with the optionally incorporated barbs (96) engage into the adjacent annulus (see page 12, line 23 - page 13, line 8; figs 6A,6B). The catheter must therefore be sufficiently flexible to be transformable between a relatively straight delivery configuration and a deployed ring with an approximate shape of an annulus of tissue (see page 13, lines 9-11; fig. 6D). Although not directly disclosed, it seems evident that the catheter's side bores (86) have to be generally placed along the outer diameter or perimeter of the ring such that the electrodes (94) optionally provided with barbs (96) can engage the surrounding annulus of tissue (see page 13, lines 9-32, fig.6D).

3. In the light of the documents cited in the search report, it is considered that the

subject-matter as claimed in independent claim 1 with claim 8 and in independent claim 16 meets the criteria mentioned in Article 33(1) PCT, i.e. it appears to be novel, involve an inventive step and to be industrially applicable. The reasons are as following:

The disclosed filament or end effector (84) of the apparatus disclosed in document D1 is made of nitinol or a spring steel material such that adopts the approximate shape of an annulus of tissue. The disclosed locking mechanism in claims 8,16 is by no means present in document D1. Apparently, its multiple key members can selectively engage one of the locks as to adapt the reduction ring to the size of the annulus, further reforming or reshaping it to the desired size and finally locking the reducing providing it with reliable capabilities for maintaining the annulus ring with the desired reduced size.

4. The following deficiencies were noted in the application:

4.1 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.

4.2 The requirements of Rule 6.3(b) PCT are not met. Independent claim 16 is not properly cast in the two-part form, with those features which in combination are part of the prior art being placed in the preamble (Rule 6.3(b)(I)PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii)PCT.

4.3 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

4.4 The vague and imprecise statement in the description on paragraphs 14,76,77 implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Article 6 PCT) when used to interpret them.